DEC 1 4 2001

Attachment 4

510(k) Premarket Notification K013282

GORE® Introducer Sheath

Premarket Notification 510(k) Summary

A. Submitted By: W.L. Gore & Associates, Inc.
P.O. Box 500
Flagstaff, AZ 86002-0500

Date Prepared: October 1, 2001

Contact: R. Larry Pratt

Phone: 928-779-2771

B. Device Name: GORE® Introducer Sheath

C. Applicant Device Description:

The GORE Introducer Sheath is designed to provide easy access to the vascular system while providing convenient temporary closure of the access site during catheter exchanges. The device allows introduction of angiographic catheters, balloon catheters, other relevant catheters, guidewires and endovascular devices into a vessel. The GORE Introducer Sheath is composed of biocompatible materials and is provided sterile.

The GORE Introducer Sheath is comprised of the introducer sheath and dilator. The introducer sheath is composed of a sheath, sheath hub and cap, and hemostasis valve. The dilator is composed of a dilator tube and dilator valve body.

D. Predicate Device:

The currently marketed FAST-CATH™ Hemostasis Introducer manufactured by St. Jude Medical, DAIG Division is cited as the predicate device which has been found to be substantially equivalent through the premarket notification process.

E. Applicant Device Labeling:

Like the predicate device, the applicant device is indicated for the introduction of guidewires, catheters and other interventional medical devices into the vasculature, and to minimize blood loss associated with such introduction.

F. Technological Characteristics:

The technological characteristics of the applicant device are substantially equivalent to those of the predicate device. The applicant device is manufactured using the same manufacturing process, the same biocompatible materials, the same quality specifications, the same packaging materials and process and the same sterilization process as the predicate device.

G. Safety and Effectiveness Conclusions:

This submission represents only a slight modification to the Instructions For Use for the applicant device as compared to the currently marketed predicate device. Therefore, the similarities between the applicant and predicate device are numerous. These equivalencies combine to justify a substantially equivalent determination.

No new types of safety and effectiveness questions are raised by the applicant device when compared to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

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W. L. Gore & Associates, Inc.
c/o Ms. Laurie Garlant
P.O. Box 500
Flagstaff, AZ 86002-0500

Re: K013282
GORE® Introducer Sheath
Regulation Number: 870.1340
Regulation Name: Introducer, Catheter
Regulatory Class: II
Product Code: DYB
Dated (Date on orig SE ltr): December 14, 2001
Received (Date on orig SE ltr): October 2, 2001

Dear Ms. Garlant:

This letter corrects our substantially equivalent letter of December 14, 2001 (date of original SE letter).

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Prepared by:myb:03/15/01

Enclosure [ONLY NEED ENCLOSURE FOR 1996 FILES THAT HAVE INDICATIONS FOR USE STATEMENTS]

Div/Branch	Last Name	Date	Div/Branch	Last Name	Date
DCD/ICDB	Hwang	3-15			
DCD/ICDB	Franczak for Born	3/15			
DCD	VcMiller	3/18/01			

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510(k) Number (if known): K013282

Device Name: GORE® Introducer Sheath

Indications For Use:

The GORE® Introducer Sheath is used to facilitate the introduction of guidewires, catheters and other interventional medical devices into the vasculature, and to minimize blood loss associated with such introduction.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K013282

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)